MODEL STANDING ORDERS

Inactivated Seasonal Influenza Vaccine (TIV)

Trivalent Types A and B

These model standing orders are current as of August 2012. They should be reviewed carefully against the most current recommendations and may be revised by the clinician signing them.

Annual influenza vaccination is recommended for *everyone* 6 months of age an older, including pregnant women.

ORDER:

- 1. Provide patient, parent or legal representative with a copy of the Vaccine Information Statement (VIS) and answer any questions. VISs in English and other languages are available online at www.immunize.org/vis.
- 2. Screen for contraindications according to Table 2.
- 3. Have adolescents and adults seated during vaccination to prevent injury should syncope occur.
- 4. If administering Fluzone Intradermal see package insert for that product. Administer all other formulations of TIV intramuscularly (IM), according to the recommended age-specific dose and schedule (Table 3). Administer IM vaccines at a 90° angle with 22-25-gauge needle. The needle length for IM injections depends upon the age, gender, and/or weight of the vaccine recipient (see Table 1 below). Always check the package insert prior to administration of any vaccine.

Table 1. Needle Length and Injection Site for IM Injection

6 month – 18 Years of Age					
Age	Needle Length	Injection Site			
Infants (6 - 12 months)	1ö	Anterolateral thigh			
Toddlers (12 months ó 35 months)	1ö ó 1¼ ö	Anterolateral thigh (preferred)			
	5/8ö ó 1ö	Deltoid			
Children (3 ó 18 y/o)	5/8ö* ó 1ö	Deltoid (preferred)			
	1ö ó 1¼ õ	Anterolateral thigh			
Adults	s 19 Years of Age and (Older			
Sex/Weight	Needle Length	Injection Site			
Male and female < 130 lbs (< 60 kg)	1ö	Deltoid			
Female 130 ó 200 lbs (60-90 kg)	1ö ó 1 ½ õ	Deltoid			
Male 130 ó 260 lbs (60 ó 118 kg)	1½ö	Deltoid			
Female > 200 lbs (>90 kg)	1½ö	Deltoid			
Male > 260 lbs (> 118 kg)	1½ö	Deltoid			

^{*} A 5/8ö needle may be used only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

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- 5. Shake the vial well before withdrawing and shake the prefilled syringe well before administering.
- 6. Administer inactivated influenza vaccine simultaneously with, or any time before or after, all other live and inactivated vaccines indicated.
- 7. If possible, observe patient for an allergic reaction for 15 20 minutes after administering vaccine.
- 8. Have personnel trained in CPR, signed emergency standing orders, epinephrine, and equipment for maintaining an airway available to treat anaphylactic reactions. See p. 12-13 of the General Recommendations on Immunization at www.cdc.gov/mmwr/pdf/rr/rr6002.pdf. Model emergency standing orders are available at www.mass.gov/Eeohhs2/docs/dph/cdc/immunization/mso_emergency_treatment.pdf
- 9. Report administration errors to the Institute for Safe Medical Practices (ISMP) via the Medication Error Reporting Program (MERP)website: http://www.ismp.org
- 10. Report clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or http://www.vaers.hhs.gov/.
- 11. See *General Protocols for Vaccine Storage, Administration, Standing Orders and Mass Immunization Clinics* http://www.mass.gov/Eeohhs2/docs/dph/cdc/immunization/mso_protocols_general.pdf

Table 2. Contraindications and Precautions to Inactivated Influenza Vaccine

Valid Contraindications for Inactivated Influenza Vaccine	Invalid Contraindications (Give Inactivated Influenza Vaccine)		
Severe allergic reaction (e.g., anaphylaxis) after a	Mild illness with or without fever		
previous dose of any influenza vaccine or to a vaccine component, including egg protein ¹ (see package insert for specific components) ²	Non-anaphylactic allergy to any component of the vaccine, including eggs ³		
Precaution to influenza vaccine: Moderate to severe acute febrile illness (temporary precaution). Guillain-Barré syndrome (GBS) ≤ 6 weeks of receiving a dose of influenza vaccine. ³	HIV infection ⁴		
	Pregnancy or breast feeding ⁵		
	Treatment with warfarin (Coumadin), theophylline, phenytoin, or aminophylline ⁶		
	Anticoagulation or bleeding disorder ⁷		

¹ See Figure 1 below. Persons who report having had reactions to egg involving such symptoms as angioedema, respiratory distress, lightheadedness, or recurrent emesis; or who required epinephrine or other emergency medical intervention, particularly those that occurred immediately or within a short time following egg exposure (minutes to hours) are more likely to have a serious systemic or anaphylactic reaction upon reexposure to egg proteins. Prior to receipt of vaccine, refer such individuals to a physician with expertise in the management of allergic conditions for further risk assessment.

Some individuals who report allergy to egg may not be egg-allergic. Those who are able to eat lightly cooked egg (e.g., scrambled egg) without reaction are unlikely to be allergic. Egg allergic persons may tolerate egg in baked products (e.g. bread, cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy. Confirm egg allergy by a consistent medical history of adverse reactions to eggs and egg-containing foods, plus a skin and/or blood testing for IgE antibodies to egg proteins.

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²Refer people with a history of anaphylaxis to any vaccine component, including eggs, to their health care provider for evaluation, desensitization and possible administration of influenza vaccine.

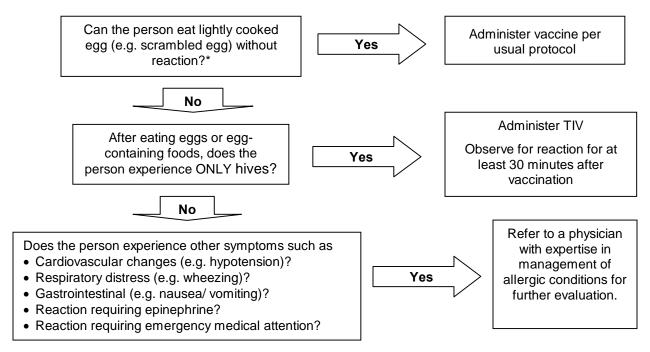
³ See Figure 1 below. Individuals who have experienced only hives following exposure to egg should

receive influenza vaccine with the following additional measures:

- a) Use TIV rather than LAIV;
- b) Vaccine should be administered by a healthcare provider who is familiar with the potential manifestations of egg allergy; and
- c) Observe vaccine recipients ≥ 30 minutes for signs of a reaction following administration of each vaccine dose.

Other measures, such as dividing and administering the vaccine by a two-step approach and skin testing with vaccine, are not necessary.

Figure 2. Recommendations Regarding Influenza Vaccination for People Who Report Allergy to Eggs, 2012-2013 Flu Season.



^{*}Persons with egg allergy might tolerate egg in baked products (e.g., bread or cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy.

⁷ Minimize the risk of bleeding after an IM injection in these patients by administering the vaccine immediately after the patient α receipt of replacement factor. Use a 23-gauge (or smaller) needle and immediately apply direct pressure to the vaccination site for ≥ 2 minutes.



⁴It may be prudent to avoid influenza vaccination of persons who are not at high risk of complications from influenza and who have experienced GBS within 6 weeks of a previous dose of influenza vaccine. As an alternative, consider antiviral chemoprophylaxis for these persons.

⁵ Flu vaccination will benefit many HIV-infected patients, including HIV-infected pregnant women, but may not induce protective antibodies in patients with advanced disease. A 2nd dose during the same flu season *does not* improve immune response in these patients.

⁶ Pregnant and postpartum women have an increased risk for complications from flu. No adverse fetal effects have been associated with flu vaccine. **Administer TIV in any trimester**.

⁷Although flu vaccine can inhibit the clearance of warfarin, theophylline, phenytoin, and aminophylline, studies show no adverse clinical effects. High-risk patients who take these medications *should* receive flu vaccine.

Table 3. Inactivated influenza vaccine dosage, by age group - United States

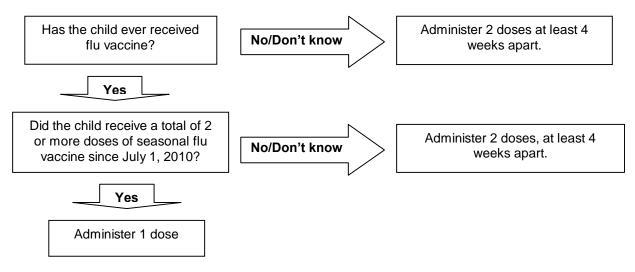
Age Group	Dose	No. of Doses		
6 ó 35 months	0.25 mL	1 or 2 ¹		
3 ó 8 years	0.5 mL	1 or 2 ¹		
≥ 9 years	0.5 mL	1		

¹ See algorithm for determining number of 2012--2013 seasonal influenza vaccine doses on page 4.

The recommendations for children 8 years of age and younger have changed for 2012 – 2013 flu season. To determine if a child 8 years and younger should receive 1 or 2 doses of flu vaccine, use the algorithm below.

Figure 2: Influenza vaccine dosing algorithm for children 6 months through 8 years of age, 2012-2013

In situations where there is limited information about a child\(\phi \) influenza vaccination history, use the algorithm below to determine whether a child 6 months through 8 years of age needs one or 2 doses of flu vaccine this season.



For simplicity, the algorithm above takes into consideration only doses of seasonal influenza vaccine received since July 1, 2010. As an alternative approach in settings where vaccination history from prior to July 1, 2010 is available, if a child 6 months through 8 years of age is known to have received at least 2 seasonal flu vaccines during any prior season, and at least 1 dose of a 2009(H1N1)-containing vaccine--i.e., either 2010-2011 or 2011-2012 seasonal vaccine or the monovalent 2009(H1N1) vaccine--then the child needs only 1 dose for 2012-2013.

Using this approach, children 6 months through 8 years of age need only 1 dose of vaccine in 2013-2013 if they have received any of the following:

- 2 or more doses of seasonal influenza vaccine since July 1, 2010; or
- 2 or more doses of seasonal influenza vaccine before July 1, 1010 and 1 or more doses of monovalent 2009 H1N1 vaccine; or



• 1 or more doses of seasonal influenza vaccine before July 1, 2010 and 1 or more doses of seasonal influenza vaccine since July 1, 2010.

Children 6 months through 8 years of age who do not meet one of these conditions require 2 doses in 2012-2013.

Table 4. Approved Influenza Vaccines for Different Age Groups¹

Manufacturer	Trade Name	Dose/ Presentation	Thimerosal (mcg Hg/0.5 mL dose)	Ovalbumin Content (mcg/ 0.5 mL dose)	Age Group
Sanofi Pasteur 800-822-2463 www.vaccineshoppe.com/	Fluzone® Inactivated	0.25 mL prefilled syringe 0.5 mL prefilled syringe	0	0.05/0.25 mL ⁴ 0.1 ⁴ 0.1 ⁴	6635 mos ≥ 36 mos
www.vaccinesnoppe.com/		0.5 mL single dose vial 5.0 mL multidose vial	0 25	0.1 0.1^4	\geq 36 mos
	Fluzone High-Dose® ² Fluzone Intradermal® ³	0.5 mL prefilled syringe 0.1 mL prefilled	0	0.1^4 $0.02/dose^2$	\geq 6 mos \geq 65 yrs
		microinjection syringe	, and the second		18-64 yrs
Novartis 800-244-7668 <u>www.novartisvaccinesdirect.</u>	Agriflu®	0.5 mL prefilled syringe	0	≤ 0.4	≥ 18 yrs
com/index	Fluvirin® Inactivated	0.5 mL prefilled syringe 5.0 mL multidose vial	≤ 1 25	≤1 ≤1	$\geq 4 \text{ yrs}$ $\geq 4 \text{ yrs}$
GlaxoSmithKline 866-475-8222 www.gskvaccinesdirect.com/ gsk/en/US/adirect/gsk	Fluarix®, Inactivated	0.5 mL prefilled syringe	0	≤ 0.05	≥ 3 yrs
	FluLuvall , Inactivated	5.0 mL multidose vial	25	<u>≤</u> 1	≥ 18 yrs
CSL Biotherapies 888-435-8633	Afluria® ⁵ , Inactivated	0.5 mL prefilled syringe 5.0 mL multidose vial	0 24.5	≤1 ≤1	$\geq 9 \text{ yrs}^1$ $\geq 9 \text{ yrs}^1$

¹ There is no preferential recommendation among any of the formulations of TIV or LAIV, but please note the recommended age groups and possible contraindications for each vaccine.

- Do not use Afluria in children aged 6 months through 8 years.
- Use other age-appropriate, licensed seasonal influenza vaccine formulations to prevent influenza in children aged 6 months through 8 years.
- If no other age-appropriate, licensed seasonal influenza vaccine is available for a child aged 5 years through 8 years who has a medical condition that increases their risk for influenza complications, Afluria may be given. Discuss the benefits and risks of influenza vaccination with the parents or caregivers before administering Afluria.



 $^{^2}$ A 0.5-mL dose contains 60 μ g of each vaccine antigen (180 μ g total).

³A 0.1-mL dose contains 9 µg of each vaccine antigen (27 µg total).

⁴ Personal communication from Sanofi Pasteur 8/21/2012.

⁵Based upon available information to date, the ACIP recommends the following:

Resources:

CDC. Prevention and Control of Influenza with Vaccines: Recommendations of the ACIP, 2012. MMWR August 17, 2012:613-618. www.cdc.gov/mmwr/pdf/wk/mm6132.pdf

CDC. Prevention and control of influenza with vaccines: recommendation of the ACIP, 2010. MMWR Early Release 2010;59 July 29, 2010:1-62. www.cdc.gov/mmwr/pdf/rr/rr5908.pdf

Package inserts for all flu vaccine formulations: www.immunize.org/fda/pa_influenza.asp

CDC. General recommendations on Immunization: recommendations of the ACIP. MMWR 2011;60(RR-2):1-61. www.cdc.gov/mmwr/PDF/rr/rr6002.pdf?source=govdelivery

CDC. Immunization of health-care personnel: recommendations of the ACIP. MMWR 2011;60(No. 7)1-46. www.cdc.gov/mmwr/pdf/rr/rr6007.pdf

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